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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,225	03/16/2004	Florencia Lim	ACSC 68062 (2242XXD)	3564
24201	7590	07/25/2007		
FULWIDER PATTON LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGELES, CA 90045			EXAMINER SANDERS, JANIS C	
			ART UNIT 1732	PAPER NUMBER
			MAIL DATE 07/25/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/802,225

Applicant(s)

LIM ET AL.

Examiner

Janis Sanders

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/16/04, 7/28/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. An initialed and dated copy of Applicant's IDS forms 1449 filed 16 March 2004 and 28 July 2006, is attached to the instant Office action.

Drawings

2. The drawings are objected to because Figure 7 is missing lines 8-8 and 9-9 as described in the specifications (pg.11). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims ^{10, 15}~~10-13~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (WO 98/03218), in view of Anderson et al. (US 5,500,180).

CAS
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As required by claim 10, Wang et al. (WO 98/03218) teaches of a balloon that may be prepared by a method wherein the manufacture of balloons is started with an extruded tubing of the thermoplastic polymer material (page 12, lines 4-5). The tubing of a thermoplastic polymer material is radially expanded under a first elevated temperature to form the balloon at a first diameter and then annealing the balloon at a second elevated temperature (abstract), suitably the second temperature is above 50°C, in the range of 70-100°C (page 4, lines 19-20). The thermoplastic polymer material may be a block copolymer material (abstract). Example 1 discloses a cooling process after the drawing and heating steps (page 13).

Wang et al. (WO 98/03218) teaches of an extrusion and an annealing of the thermoplastic tube. However, the reference does not teach of two elevated heating steps after the annealing process, as required by claim 10.

Anderson et al. (US 5,500,180) teaches a method of making balloon catheters using block copolymers. The parison is formed from the polyurethane marketed by The Dow Chemical Company under the trade name PELLETHANE 2363-75D and radially expanded at a first temperature of about 90-100°C. A second heating step (the heat set step) would preferably be conducted at a temperature range higher than the first, at about 105-120°C (col. 10, lines 10-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Wang et al. to include the steps of two additional elevated heating steps of the extruded tube, with the second elevated temperature being of equal or greater degrees than the first elevated temperature, as taught by Anderson et al. One of ordinary skill would have been motivated to do so because the first elevated temperature is to ensure a second radial expansion of the balloon catheter will reach a desired diameter (Anderson: col. 9, lines 15-23) . The second elevated heating step, of equal or greater temperature, is to set the shape of the extruded tubular balloon once the desired shape has been obtained from previous radial expansion steps (Anderson: col. 9, lines 60-67). Because both references are concerned the method of making a thermoplastic tube to be used as a balloon catheter, one would have a

reasonable expectation of success from the combination, one would have a reasonable expectation of success from the combination.

5. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (WO 98/03218) in view of Anderson et al. (US 5,500,180) as applied to claim 10 above, and further in view of Wang et al. (US 5,500,181).

Wang et al. (WO 98/03218) in view of Anderson et al. teaches the method of claim 10, as discussed above.

Wang (WO 98/03218) in view of Anderson et al. does not teach of annealing at a temperature of 55°C and for 16-24 hours.

Wang et al. (US 5,500,181) teaches a process that the assembled balloon catheter must undergo is the annealing technique. The balloon catheter is submerged in water or air at a temperature in the range of 25-100°C. However, it should be understood that the temperature and time required for the annealing process, depends upon the size of the balloon that is being processed (col. 11, lines 31-42).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Wang et al (WO 98/03218) in view of Anderson et

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al to include a time and temperature for the annealing process as taught by Wang et al. (US 5,500,181). One of ordinary skill would have been motivated to do so because the annealing process causes the length and the diameter of the balloon to decrease and the wall thickness to increase. Also, annealing establishes the molded articles with good characteristics of high heat resistance, friction melt resistance, hydrolysis resistance and compression set. Because all references are concerned with the method of making a thermoplastic tube to be used as a balloon catheter, one would have a reasonable expectation of success from the combination.

Wang et al (WO 98/03218) as modified Anderson et al. (US 5,500,180), and further modified by Wang et al. (US 5,500,181) does not teach of the following parameters: annealing the extruded tubular product for 16 to 24 hours. However, one of ordinary skill would recognize that the parameters would affect the resulting balloon catheter's temperature and dimensional stability. The annealing process causes the length and the diameter of the balloon to decrease and the wall thickness to increase resulting in molded articles with good characteristics of high heat resistance, friction melt resistance, hydrolysis resistance and compression set.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the instantly claimed ranges through process optimization, since it has been held that when the general condition of a claim is disclosed in the prior art, discovering the optimal or workable ranges involves only routine skill in the art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Remarks

6. No claim is allowed.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iwata et al (US 5,780,573), Herweck et al. (US 6,395,208), and Ozaki et al. (US 5,498,377) disclose methods for producing a molded thermoplastic article.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janis Sanders whose telephone number is 571-272-7145. The examiner can normally be reached on M-F 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janis Sanders
Patent Examiner
Art Unit 1732

7/17/07


CHRISTINA JOHNSON
SUPERVISORY PATENT EXAMINER
7/23/07